

Bimeda, Inc. Division of Cross Vetpharm Group Bimectin Pour-On for Cattle (Ivermectin)
ANADA 200-318, Approved by FDA

Indications: Bimectin® (ivermectin) Pour-On applied at the recommended dose level of 500 mcg/kg is indicated for the effective treatment and control of these parasites.

Gastrointestinal Roundworms

<i>Ostertagia ostertagi</i> (including inhibited state)	(adults and L ₄)
<i>Haemonchus placei</i>	(adults and L ₄)
<i>Trichostrongylus axei</i>	(adults and L ₄)
<i>T. colubriformis</i>	(adults and L ₄)
<i>Cooperia oncophora</i>	(adults and L ₄)
<i>Cooperia punctata</i>	(adults and L ₄)
<i>Cooperia surnabada</i>	(adults and L ₄)
<i>Strongyloides papillosus</i>	(adults)
<i>Oesophagostomum radiatum</i>	(adults and L ₄)
<i>Trichuris spp.</i>	(adults)

Lungworms

<i>Dictyocaulus viviparus</i>	(adults and L ₄)
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Cattle Grubs

<i>Hypoderma bovis</i>	(parasitic stages)
<i>H. lineatum</i>	

Mites

<i>Sarcoptes scabiei var. bovis</i>

Lice

Linognathus setosus

Linognathus vituli

Haematopinus eurysternus

Damalinia bovis

Solenopotes capillatus

Horn Flies

Haematobia irritans

Persistent Activity: Bimectin® (ivermectin) Pour-On has been proved to effectively control infections and to protect cattle from re-infection with: *Oesophagostomum radiatum* and *Dictyocaulus viviparus* for 28 days after treatment; *Cooperia punctata* and *Trichostrongylus axei* for 21 days after treatment; *Ostertagia ostertagi*, *Haemonchus placei*, *Cooperia oncophora* and *Cooperia surnabada* for 14 days after treatment; *Damalinia bovis* for 56 days after treatment.

Treatment of Cattle for Horn Flies: Bimectin® (ivermectin) Pour-On controls horn flies (*Haematobia irritans*) for up to 28 days after dosing. For best results Bimectin® (ivermectin) Pour-On should be part of a parasite control program for both internal and external parasites based on the epidemiology of these parasites. Consult your veterinarian or an entomologist for the most effective timing of applications.

Dosage: The dose rate is 1mL for each 22lb of body weight. The formulation should be applied along the topline in a narrow strip extending from the withers to the tailhead.

Administration:

Squeeze-Measure-Pour System (33.8 fl oz 1 Liter Bottle with 25 mL Measuring Cap)

Attach metering cap to the bottle.

Select the correct dose rate by rotating the adjuster cap in either direction to position the dose indicator to the appropriate dose.

Gently squeeze the bottle to fill to level (any excess will return to the bottle) and then tip and apply to animal along topline.

BackPack (84.5 fl oz/2.5 Liter Pack and 169 fl oz/5 Liter Pack)

Connect the applicator gun to the backpack as follows: Attach the open end of the draw-off tubing to the dosing equipment. (Because of the solvents used in the formulation, only the Protector Drench Gun from Instrument Supplies Limited, or equivalent, is recommended. Other applicators may exhibit compatibility problems resulting in locking, incorrect dosage or leakage).

Replace the shipping cap with the draw-off cap and tighten down.

Attach draw-off tubing to the draw-off cap.

Gently prime the applicator gun, checking for leaks.

Follow the manufacturer's directions for adjusting the dose.

When the interval between uses of the applicator gun is expected to exceed 12 hours, disconnect the gun and draw-off tubing from the product container and empty the product from the gun and tubing back

into the product container. To prevent removal of special lubricants from the Protector Drench Gun, the gun and tubing must not be washed.

Free standing bottle (338 fl oz/10 Liter bottle and 676 fl oz/20 Liter bottle)

Connect the applicator gun to the bottle as follows: Attach the open end of the draw-off tubing to the dosing equipment. (Because of the solvents used in the formulation, only the Protector Drench Gun from Instrument Supply Limited, or equivalent is recommended. Other applicators may exhibit compatibility problems resulting in locking, incorrect dosage or leakage.)

Replace the shipping cap with the draw-off cap and tighten down.

Attach draw-off tubing to the draw-off cap.

Gently prime the applicator gun, checking for leaks.

Follow the manufacturer's directions for adjusting the dose.

When the interval between uses of the applicator gun is expected to exceed 12 hours, disconnect the gun and draw-off tubing from the product container and empty the product from the gun and the tubing back into the product container. Replace the draw-off cap with the shipping cap. To prevent removal of special lubricants from the Protector Drench Gun, the gun and tubing must not be washed. If the shipping cap is to be used with the faucet spigot installed (which can be used for refilling the 33.8 fl oz/1 Liter Bottle, 84.5 fl oz/2.5 Liter Pack or 169 fl oz/5 Liter Pack), pop the plastic seal out of the center of the shipping cap, screw in the threaded spigot, and tighten down. Store the bottle upright, with the spigot in the off position between uses.

Mode of Action: Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA). The margin of safety for compounds of this class is attributable to the fact that mammals do not have the glutamate-gated chloride channel, the macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channel and they do not readily cross the blood-brain barrier.

Animal Safety: Studies conducted in the U.S.A. have demonstrated the safety margin for ivermectin. Based on plasma levels, the topically applied formulation is expected to be at least as well tolerated by breeding animals as is the subcutaneous formulation which had no effect on breeding performance.

RESIDUE WARNING: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

WARNING! NOT FOR USE IN HUMANS.

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

Keep this and all drugs out of the reach of children.

Restricted Drug (California)-Use Only as Directed

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS or for assistance contact Bimeda, Inc. at 1-888-524-6332.

WARNING! FLAMMABLE!

KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME, AND OTHER SOURCES OF IGNITION

PRECAUTIONS:

Store at 20°C-25°C (68°F-77°F), excursions permitted between 15°C and 30°C (between 59°F-86°F).

Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however such exposure should be minimized and protect from light.

Use only in well-ventilated areas or outdoors.

Close container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when Bimectin® (ivermectin) Pour-On is stored at temperatures below 32° F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g., caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, Bimectin® (ivermectin) Pour-On is not recommended for use in species other than cattle.

When to Treat Cattle with Grubs: Bimectin® (ivermectin) Pour-On effectively controls all stages of cattle grubs. However, proper timing of treatment is important. For the most effective results, cattle should be treated as soon as possible after the end of the heel fly (warble fly) season. While this is not peculiar to ivermectin, destruction of *Hypoderma* larvae (cattle grubs) at the period when these grubs are in vital areas may cause undesirable host-parasite reactions. Killing *Hypoderma lineatum* when it is in the esophageal tissues may cause bloat; killing *H. bovis* when it is in the vertebral canal may cause staggering or paralysis. Cattle should be treated either before or after these stages of grub development.

Cattle treated with Bimectin® (ivermectin) Pour-On at the end of the fly season may be re-treated with Bimectin® (ivermectin) Pour-On during the winter without danger of grub-related reactions. For further information and advice on a planned parasite control program, consult your veterinarian.

Environmental Safety: Studies indicate that when ivermectin comes in contact with soil, it readily and tightly binds to the soil and becomes inactive over time. Free ivermectin may adversely affect fish or certain aquatic organisms. Do not permit cattle to enter lakes, streams, or ponds for at least 6 hours after treatment. Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

As with other avermectins, ivermectin is excreted in the dung of treated animals and can inhibit the reproduction and growth of pest and beneficial insects that use dung as a source of food and for reproduction. The magnitude and duration of such effects are species and life-cycle specific. When used according to label directions, the product is not expected to have an adverse impact on populations of dung-dependant insects.

Bimectin (Ivermectin) Pour-On
ANADA 200-318, Approved by FDA

Contains 5mg ivermectin/mL

Parasiticide

Kills: Roundworms (including Brown Stomach Worm), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies, and sarcoptic mange mites in cattle

See package insert for the complete indications and use directions.

Recommended dose 1mL per 22lb of body weight.

Take Time Observe Label

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

Warning! Flammable! Keep away from heat, sparks, open flame and other sources of ignition.

Not for use in humans.



Bimectin[®]

(ivermectin)

POUR-ON FOR CATTLE
Contains 5 mg ivermectin/mL
Parasiticide

Contains 800-550 lb Doses

Kills: Roundworms (including Brown Stomach Worm), Lungworms,
Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

INDICATIONS: For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

See package insert for the complete indications and use directions.

Recommended Dose: 1 mL per 22 lb of body weight.

RESIDUE WARNING: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

WARNING! NOT FOR USE IN HUMANS.

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

Keep this and all drugs out of the reach of children.

**WARNING! FLAMMABLE! KEEP AWAY FROM HEAT, SPARKS,
OPEN FLAME AND OTHER SOURCES OF IGNITION.**

Restricted Drug (California) - Use Only as Directed

PRECAUTIONS: Store at 20°-25°C (68°-77°F), with the excursion information included on the package insert and protect from light. Use only in well-ventilated areas or outdoors. Close container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced. Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when Bimectin[®] (ivermectin) Pour-On is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

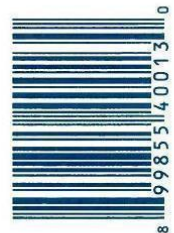
Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g., caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, Bimectin[®] (ivermectin) Pour-On is not recommended for use in species other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

TAKE TIME  OBSERVE LABEL DIRECTIONS

Bimectin[®] is a Registered Trademark of Bimeda, Inc.
Bimeda Inc. is a Division of Cross Vetpharm Group Ltd.
Product No.: 1BIM009 8BIM005 Rev: 8/10



ANADA 200-318, Approved by FDA

Net Contents: 676 fl. oz. (20 Liter)

**WARNING! FLAMMABLE! KEEP AWAY FROM HEAT, SPARKS,
OPEN FLAME AND OTHER SOURCES OF IGNITION.**
WARNING! NOT FOR USE IN HUMANS.

Manufactured by:
Bimeda, Inc.
Le Sueur, MN 56058

 **Bimeda**

LOT:
EXP:

Bimectin (Ivermectin) Pour-On is available in a 33.8fl oz/1Liter Bottle with a measure-pour system, an 84.5 fl oz/2.5Liter Pack, a 169 fl oz/5Liter Pack, a 338 fl oz/10Liter Bottle and a 676 fl oz/20Liter Bottle intended for use with appropriate automatic dosing equipment.

BIMECTIN POUR-ON

ivermectin solution

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:6 1133-60 14
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
Ivermectin (UNII: 8883YP2R6D) (Ivermectin - UNII:8883YP2R6D)			Ivermectin	5 mg in 20 L
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61133-6014-2	20 L in 1 CONTAINER		
2	NDC:61133-6014-5	1 L in 1 CONTAINER		
3	NDC:61133-6014-6	1 L in 1 CARTON		
4	NDC:61133-6014-7	2.5 L in 1 CONTAINER		
5	NDC:61133-6014-8	2.5 L in 1 CARTON		
6	NDC:61133-6014-3	5 L in 1 CARTON		
7	NDC:61133-6014-1	5 L in 1 CONTAINER		
8	NDC:61133-6014-4	10 L in 1 CONTAINER		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA		ANADA200318	10/01/2009	

Labeler - Bimeda, Inc. Division of Cross Vetpharm Group (060492923)

Revised: 8/2015

Bimeda, Inc. Division of Cross Vetpharm Group